

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)		
	)	Art Unit:	1804
Inventors: Kucherlapati et al.	)		
	)	Examiner:	Ziska, Suzanne., Ph.D.
Serial No.: 08/031,801	)		
	)		
Filed: March 15, 1993	)		
	)		
Entitled: GENERATION OF	)		
XENOGENEIC ANTIBODIES	)		
	)		
	)		

# 34

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**PETITION UNDER 37 C.F.R. § 1.181**

Petitioners respectfully request the Assistant Commissioner for Patents to reverse the September 26, 1996 decision of the Group Director of Group 1800. Petitioners further request that the Assistant Commissioner order the Group Director and the Examiner in charge of the present application to issue a Notice of Allowance/Base Issue Fee Due to be mailed to Petitioners, and, upon payment of the Issue Fee, to issue promptly a patent corresponding to the allowable claims in the present application.

**I. BACKGROUND**

**A. Petitioners' Contentions**

Petitioners contend that the present application has been improperly suspended by the U.S. Patent and Trademark Office (the "PTO") in violation of M.P.E.P. § 2303. The present application contains claims that have been found to be allowable to Petitioners and that have an effective filing date of more than seven months before the filing date of a junior party. Nevertheless, almost seven years after the application's effective filing date, during which the application has been repeatedly suspended and reopened, the application has been suspended once again pending a declaration of

interference. While the present application and five related applications have been suspended,<sup>1</sup> the junior party competitor, GenPharm International, Inc., has received two patents covering closely related technologies. GenPharm, moreover, has recently instituted a patent infringement action against Abgenix, Inc., the wholly owned subsidiary of Cell Genesys, Inc., the assignee of the present application.

The Group Director's Decision approving the declaration of interference and denying Petitioners' request to issue a patent is in error, and has compounded the unfair delay to which the present application has been subjected. Petitioners therefore request that the Assistant Commissioner reverse the Group Director's Decision and order the issuance of the present application as a patent to Petitioners.

***B.     The Invention***

The invention at issue is of great importance to public health and welfare. As described in the present application, the invention will permit the development of fully human monoclonal antibodies from transgenic mammals. These antibodies promise significant advantages over other therapies for a variety of diseases.

The present invention relates to transgenic mammals (such as mice) that produce human immunoglobulin (Ig) molecules (i.e., antibodies) to the exclusion of the mammal's own (or endogenous) Ig molecules. In particular, the present application contains claims that are directed to a transgenic non-primate mammal that contains a modified genome. The genome in the mammal is modified in such a way that the mammal is incapable of producing functional Ig molecules. Specifically, the genome is modified through deletion of the joining or J region of the endogenous heavy chain Ig locus. *See* Claim 83. The application claims:

A transgenic nonprimate mammal comprising in its genome a modified genome, wherein said modification comprises a deletion of all or substantially all of the J region of at least one copy of the immunoglobulin heavy chain locus, wherein said deletion results in the inability of said copy of the locus to rearrange or to produce a functional message encoding an immunoglobulin heavy-chain subunit.

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<sup>1</sup> To date, five of Petitioners applications have been suspended: U.S. Patent Application Serial Nos. 07/922,649, 08/112,848, 08/464,582, 08/463,191, and 08/462,513.

*Id.* In accordance with dependent claims of the invention, the mammal can additionally include a xenogeneic Ig gene locus (i.e., antibody genes from another mammal such as a human). *See* Claims 86, 95-97, and 101-103. The mammal, in one embodiment, is a mouse. *See* Claims 89-94.

**C. The Filing Date and the Prosecution of the Applications**

The present application is a continuation-in-part of U.S. Patent Application Serial No. 07/919,297, filed on July 24, 1992, which is a continuation-in-part of U.S. Patent Application Serial No. 07/610,515, filed on November 8, 1990, which is a continuation-in-part of U.S. Patent Application Serial No. 07/466,008, which was filed on January 12, 1990 (the “‘008 Application”). Thus, the effective filing date of the present application is January 12, 1990. The ‘008 Application, and the other cases in the lineage, presented claims substantially similar to the above-described claims (i.e., claims that included the inactivation of an endogenous Ig locus coupled with the inclusion of a xenogeneic Ig locus). These claims were not elected for prosecution on the merits until the present application.

Substantive prosecution of the present application began in June 1994. Successive suspensions, reopenings, and delays followed. In January 1995 the Examiner noted in an Examiner’s Interview Summary Record that “an interference on Claim 101 is established.” The Examiner apparently suspended the prosecution of the application pending the potential declaration of an interference. Over nine (9) months later, on November 17, 1995, the Examiner informed Petitioners’ patent attorney that prosecution on the merits would be reopened to reject the claims over prior art, and faxed a draft of an Office Action alleging the same to Petitioners’ patent attorney. On December 13, 1995, one of Petitioners (Dr. Kucherlapati), Petitioners’ patent attorney, and others conducted an Interview with the Examiner and Biotechnology Specialist, Dr. Richard Schwartz. During the Interview, Petitioners stressed the importance of the technology in the application. The Examiner’s response led Petitioners and Petitioners’ patent attorney to believe that prompt action by the PTO would be forthcoming.

Further delay followed. From December 1995 until March 1996, Petitioners’ patent attorney was in frequent contact with the Examiner, Dr. Schwartz, and the Group Director urging actions consistent with discussions that had taken place in the Interview. On March 1, 1996, the Examiner

finally took action. In a Communication, the Examiner noted that Claim 101 was allowable but suspended *ex parte* prosecution pending a potential interference.

On April 30, 1996, an agreement was reached in a telephonic interview with the Examiner with respect to certain amendments to Claims 83-97 and 101-103; these amendments placed the application in condition for allowance. The Examiner also issued a Notice of Allowability and an Examiner's Amendment for such Claims.

As of April 30, 1996, the written record indicated that the suspension instituted on March 1, 1996 had been superseded by the Notice of Allowability and Examiner's Amendment of April 30, 1996. Petitioners' patent attorney, however, was subsequently informed during telephone conversations with the Examiner that the application remained suspended.

**D. Request for Expedited Notice of Allowance and Issuance of Patent**

On August 7, 1996, Petitioners filed, via facsimile, with the Group Director of Group 1800, a Request for Expedited Notice of Allowance and Issuance of Patent. In the Request, Petitioners made reference to a potentially competing patent application: U.S. Patent Application Serial No. 07/574,748, filed on August 29, 1990 by Drs. Kay and Lonberg and assigned to GenPharm International (the "'748 Application"). Such application was obtained as a priority document to international patent application WO/92/03918, which was published on March 19, 1992.

In their request, Petitioners noted that the '748 Application was filed more than seven months after the effective filing date of the present application. Relying on the clear language of M.P.E.P. § 2303, Petitioners asserted that no interference should be declared between Petitioners' application and the '748 Application or its progeny because more than six months had passed between the applications' effective filing dates. The Request urged that a formal Notice of Allowance in connection with the present application should be mailed to Petitioners and that a patent should be promptly issued thereon.

**E. Decision on Request**

On September 26, 1996, the Group Director issued a Decision denying Petitioners' Request.

The Group Director premised his decision as follows:

First it is noted that at this time it would be improper to reveal information about the interfering application. Therefore, requester's assumptions noted above cannot be confirmed or denied. Second MPEP § 2303 clearly indicates that for inventions of a simple character, interference will not be declared if there is a difference of more than 3 months between the effective filing dates of the interfering applications and for inventions in other cases, interferences will not be declared if there is a difference of more than 6 months between the effective filing dates of the interfering applications, except in exceptional circumstances, as determined and approved by the group director. This difference based on the character of invention at least implies that an exceptional situation would be present for inventions of an extremely complex nature. The invention in this case is a transgenic animal which is extremely complex in nature and therefore would warrant the declaration of an interference even if the difference between the effective filing dates of the interfering applications were more than six months. Third, as group director, I am aware of the interfering applications, and I approve of the declaration of interference.

Petitioners submit that the Decision erroneously interprets M.P.E.P § 2303 and must be reversed.

**II. ARGUMENT**

Failure to reverse the Group Director's Decision and failure to issue Petitioners' application as a patent will significantly undermine Petitioners' ability to secure the financing and partnerships that are necessary for the clinical and commercial development of novel pharmaceutical products for the treatment of chronic and life threatening diseases. In addition, the Group Director's Decision violates both the letter and spirit of M.P.E.P. § 2303, creates an inconsistency with 37 C.F.R. § 1.608(b), and contravenes fundamental policies of patent law. A failure to reverse the Decision would constitute manifest injustice.

A. *Failure to Issue a Patent to Petitioners Significantly Undermines Petitioners' Ability to Secure Financing and Partnerships Needed for the Clinical and Commercial Development of its Products*

Cell Genesys, Inc., the assignee of the present application, was formed in 1988. Dr. Kucherlapati, one of the inventors of the present application, was a founder of the Company. One of the core programs of the company was the research and development of a transgenic mouse that could produce human antibodies without producing endogenous antibodies.

Cell Genesys has spent tens of millions of dollars in the development of the technology described in the '008 Application. In August 1996, based on the progress in this program, Cell Genesys formed a wholly owned subsidiary, Abgenix, Inc., to develop and commercialize antibody products and to enable Cell Genesys to focus on its core business in gene therapy. Cell Genesys is in the process of formally assigning all of its rights in the antibody technology to Abgenix.

Abgenix has a colony of mice that do not produce endogenous antibodies but produce fully human antibodies. Such mice were prepared substantially as described in the '008 Application. Such mice produce human antibodies to a wide range of antigens. The antibodies have affinities exceeding  $10^9$  and often  $10^{10}$  and greater. Conventional technologies, although able to achieve similar affinities, produce antibodies that have a substantial mouse (or murine) component and are recognized as foreign by the human immune system. This can lead allergic responses as well as the rapid clearance of such antibodies from the patient's bloodstream. Antibody clearance rates and allergic response become particularly relevant in the treatment of chronic diseases that require multiple doses of antibodies.

Human antibodies in accordance with the invention, and as produced by Petitioners' mice, will not produce allergic reactions associated with antibodies which contain at least some mouse protein. Accordingly, antibodies produced by Petitioners' mice offer a substantial benefit to the treatment of a wide range of chronic and life threatening diseases. To make this goal a reality, the antibodies must be moved into human clinical trials in patients with various diseases. This requires an investment of tens to hundreds of millions of dollars.

To secure the necessary protection for its technology, Petitioners have worked with the PTO to overcome all objections. Despite Petitioners' priority date that is more than six months senior to

GenPharm's filing date (a company that we believe derived the technology from Cell Genesys and whose mice produce antibodies of inferior clinical quality), Petitioners have been prevented from obtaining patent protection; meanwhile GenPharm has already obtained two patents on related technologies.

Great difficulties face any company endeavoring to bring a novel pharmaceutical product to market. The PTO should not additionally burden this quest by disregarding its own rules and unfairly delaying Petitioners' senior application. For the reasons discussed herein the Group Director's Decision should be reversed.

***B.     The Group Director Erroneously Applied M.P.E.P. § 2303***

***1.     M.P.E.P § 2303***

The Manual of Patent Examining Procedure instructs that:

Interferences will not be declared between pending applications if there is a difference of more than 3 months in the effective filing dates of the oldest and next oldest applications, in the case of inventions of simple character, or a difference of more than 6 months in the effective filing dates of the applications in other cases, except in exceptional situations, as determined and approved by the group director.

M.P.E.P. § 2303 (*emphasis supplied*).

In the present case, assuming that the interfering application is GenPharm's '748 Application, or one of its progeny,<sup>2</sup> there is a difference of more than six months between the effective filing dates of the present application and the interfering application. Therefore, pursuant to M.P.E.P. § 2303, an interference shall not be declared, and the present application should be issued as a patent, absent the existence of an "exceptional situation."

***2.     No "Exceptional Situation" Exists in Connection with the Present Application***

There is no "exceptional situation" under Section 2303 to justify denying Petitioners the

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<sup>2</sup> Having worked extensively in the field for many years, Petitioners have seen no other pending applications and know of no other development programs surrounding the filing dates of the priority applications that so squarely present subject matter that would be likely to interfere with Petitioners' applications as the GenPharm applications. Thus, Petitioners believe that there is a solid basis for Petitioners' assumption.

benefit of their earlier effective filing date. First, the Group Director's interpretation of what constitutes an exceptional situation violates the basic policies underlying Section 2303 and 37 C.F.R. § 1.608. Second, the fact that the technology at issue involves transgenic animals no more justifies declaring this an "exceptional situation" than would any other high or cutting-edge technology; to apply such a standard would vitiate the rule and lead to its arbitrary and capricious application. Third, when the term "exceptional situation" is properly construed in light of decisions by the Board of Patent Appeals and Interferences and by the Commissioner interpreting similar language, it is evident that the intent of the language is to prevent injustice, not to create it. Fourth, and perhaps most significantly, it is our understanding that the PTO is now applying the "six-month rule" in M.P.E.P. § 2303 without any exception.

***a.     The Group Director's Decision Violates Basic Policies Underlying  
M.P.E.P. § 2303 and 37 C.F.R. § 1.608***

A central objective of U.S. patent law is to grant exclusive rights to an invention, for a limited time, to the first and true inventor. In exchange for this limited legal monopoly, the inventor must disclose an enabling description of his or her invention. Various aspects of both patent law and procedure encourage inventors to file applications early and not to abandon, suppress, or conceal their inventions. *Naber v. Cricchi*, 196 U.S.P.Q. 294, 567 F.2d 382, 385 n.5 (CCPA 1977) ("Public policy favors the early disclosure of inventions."), *cert. denied*, 439 U.S. 826 (1978); *Howarth v. Lee*, 195 U.S.P.Q. 701, 564 F.2d 948, 950 (CCPA 1977) ("Early public disclosure [of inventions] is 'the linchpin of the patent system.'").

For example, under the reasonable diligence standard, 35 U.S.C. § 102(g), the interest in rewarding the first inventor is balanced with the "public's interest in the earliest possible disclosure of innovation." *Griffith v. Kanamaru*, 2 U.S.P.Q. 2d 1361, 816 F.2d 624 (Fed. Cir. 1987). Patent rules on proof of priority emphasize the importance of the date of the filing of an application - the constructive reduction to practice - because this is the date on which the invention is revealed to the public. The date when an application adequately disclosing the subject matter is filed is presumed to be the date of invention. *Bates v. Coe*, 98 U.S. 31, 34 (1978) ("[T]he presumption in respect to invention . . . is that it was made at the time the application was filed. . ."); *Abrutyn v. Giovanniello*,

29 U.S.P.Q. 2d 1615, 15 F.3d 1048 (Fed. Cir. 1994) (“[A] rebuttable presumption exists that the inventors made their invention in accordance with the order of their filing dates.”); *see also* 37 C.F.R. § 1.657.

An application’s filing date raises certain presumptions in interference proceedings as well. Title 37 C.F.R. § 1.608 places the burden to prove an interference with an issued patent on a junior party applicant whose application is filed more than three-months (37 C.F.R. § 1.608(a)) and additional burdens on applications filed more than six-months (37 C.F.R. § 1.608(b)) after the effective filing date of the patent. Where the junior application is filed more than six-months after the senior applications, the junior party must provide “evidence . . . which demonstrate[s] that applicant is *prima facie* entitled to judgment relative to the patentee and an explanation stating with particularity the basis upon which the applicant is *prima facie* entitled to the judgment.” 37 C.F.R. § 1.608(b). If the junior party applicant relies on priority of invention, he or she is required to provide evidence in the form of affidavits by the applicant and by one or more corroborating witnesses supported by documentary evidence. *Id*; *see also* M.P.E.P. §§ 2308, 2308.01, and 2308.02.

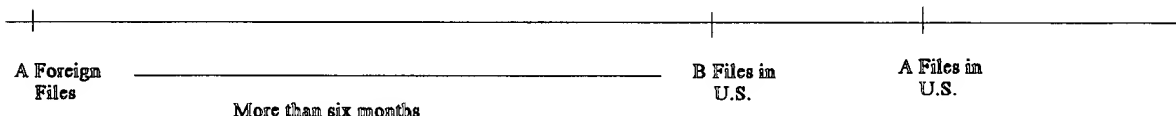
Section 2303 of the M.P.E.P. contains a similar deference to filing dates, establishing a presumption of priority for the earlier-filed application. Section 2303 states that a three-month rule applies to inventions of a simple character; for *all other inventions*, a six-month rule applies. This rule is clearly designed to be in harmony with 37 C.F.R. § 1.608(b); if there is more than six months between the effective filing dates of the competing applications, the senior party application should issue and the junior party should bear the burden of provoking an interference and providing evidence that he or she is *prima facie* entitled to judgment under 37 C.F.R. § 1.608(b).

Both 37 C.F.R. § 1.608(b) and M.P.E.P. § 2303 emphasize the importance of early applications, and incorporate the public policy in favor of early filing and public disclosure that runs throughout U.S. patent laws. To deny Petitioners the proper construction and application of 37 C.F.R. § 1.608 and M.P.E.P. § 2303 runs counter to a fundamental policy of U.S. patent law. The Group Director’s Decision is therefore in error and must be reversed.

b. *In Order for M.P.E.P. § 2303 to be Consistent with the Code of Federal Regulations, the Term “Exceptional Situation” must Focus on Prejudice to the Junior Party and No Such Prejudice Exists in this Case*

Section 2303 provides but a single example of an “exceptional situation”. It states that “[o]ne such exceptional situation would be where one application has the earliest effective filing date based on foreign priority and the other application has the earliest effective United States filing date.” Such facts are clearly not present in this case. Further, the example illustrates that an “exceptional situation” under Section 2303 must be one that would result in unfair prejudice to the *junior party*. This interpretation of “exceptional situation” is the only one that prevents the frustration of the public policy behind M.P.E.P. § 2303 and 37 C.F.R. § 1.608.

The focus on unfair prejudice to the junior party is illustrated by the sole example of “exceptional situation” illustrated in M.P.E.P. § 2303, which is shown schematically below:



In the example, the junior U.S. applicant (A) is the senior party only because of his or her earlier foreign filing date. At least pre-GATT, this fact upset the ordinary presumption that the first to file in the U.S. is the senior party. Because A could not necessarily demonstrate earlier invention based on its foreign acts of invention, to strictly apply the six-month rule in Section 2303 could result in unfair prejudice to the junior party (B). It is only this unfair prejudice that should constitute an “exceptional situation” under Section 2303.

Interpreting “exceptional situation” as requiring a showing of unfair prejudice is consistent with decisions using the term “exceptional circumstances.” See *Djeredjian v. Kashi Co.*, 21 U.S.P.Q. 2d 1613 (Comm’r 1991) (examining Fed. R. Civ. P. 60(b) in a motion for relief from a

default judgment in a trademark cancellation proceeding, and concluding that “[r]elief from a judgment under Fed. R. Civ. P. 60(b) is an extraordinary remedy to be granted in the court’s discretion only in exceptional circumstances. . . . Among the factors to be considered . . . are the following: (1) whether the non-defaulting party will be prejudiced, (2) whether the default was willful, and (3) whether defendant has a meritorious defense.”); *see also Weiffenbach v. Logan*, 27 U.S.P.Q. 2d 1613 (Comm’r 1993) (denial of hearing in a disciplinary action against a practitioner would only be allowed if there existed “exceptional circumstances” as to justify denial of the statutorily mandated hearing).

In light of the above considerations, a senior party applicant would not be denied the benefits of the six-month rule except in the exceptional situation in which applying the six-month rule would cause unfair prejudice to the junior party. No such circumstances exist in this case, for the Group Director’s Decision rests entirely on the alleged complexity of the invention. Accordingly, the Group Director’s Decision is in error and must be reversed.

c. *Complexity of Technology Does Not Create an “Exceptional Situation”*

In his Decision, the Group Director opined that because M.P.E.P. § 2303 presented a bifurcated scheme based on the complexity or character of invention, it “imply[d] that an exceptional situation would be present for inventions of an extremely complex nature.” As discussed above, complexity of invention cannot provide a basis to ignore the requirements of 37 C.F.R. § 1.608(b).

Even assuming *arguendo* that the Group Director’s interpretation is reasonable, the question arises of when is an invention “extremely complex in nature”? Just because the present invention relates to a transgenic mammal does not make it inherently more complex than an invention in molecular biology, synthetic organic chemistry, or computer technology. In fact, the claims presented in the present application call for a molecular biological manipulation that results in a particular physiological manifestation within the mammal (i.e., “inability of . . . the locus to rearrange or to produce a functional message encoding an [Ig] heavy-chain subunit”). *See* Claim 83. To follow the Group Director’s interpretation of M.P.E.P. § 2303 to its logical conclusion, virtually every technology in Group 1800 (and many other groups) would represent an “exceptional situation” due

to its complexity, and M.P.E.P. § 2303 is inapplicable to such Examining Groups. Such an interpretation is wrong in law and in practice within the PTO. This clearly could not be the intention of the Group Director.<sup>3</sup>

M.P.E.P. § 2303, taken in combination with the example given in the section, presents a clear legal delineation of what constitutes an exceptional situation. M.P.E.P. § 2303 does not, and should not, address the subjective complexity of a subject technology. Nor would the subjective assessment of a technology's complexity afford an applicant, an Examiner, or a Group Director guidance as to whether the six-month rule applies.

Thus, to allow such an interpretation undermines the policy considerations discussed above, vitiates the effectiveness and purpose of 37 C.F.R. § 1.608, and can lead to the arbitrary application of M.P.E.P. § 2303. Accordingly, the Group Director's Decision is in error and must be reversed.

*d.     The PTO is Now Applying the Six-Month Rule Without Exception  
in all Cases*

Perhaps most significantly, it is our understanding that the PTO is now applying the six-month rule in 37 C.F.R. § 1.608 and M.P.E.P. § 2303 without exception in all cases. It is our understanding that this policy directive flows from the tremendous backlog of cases at the Board of Patent Appeals and Interferences and from specific requests from the Board to the Examination Division to adhere to M.P.E.P. § 2303.

If it is true that this policy changed after Petitioners' application was first forwarded to the Board, there is simply no basis to avoid applying the rule to the current case. Petitioners and Petitioners' patent counsel are sensitive to the needs of the PTO for consistency. Nevertheless, the Group Director's erroneous Decision cannot be left to stand. Further, it is unjust to Petitioners not to apply the six-month rule to the facts of the present case. Accordingly, the Decision must be reversed and the Examiner and the Group Director should be ordered to promptly mail a Notice of

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<sup>3</sup> Moreover, were the Assistant Commissioner to affirm the Group Director's Decision, patent applicants would be able to argue that a senior party's application should not issue, even if filed more than six months before the junior party's application, simply because the technology in question is "extremely complex." This could be asserted with respect to applications involving virtually any high or cutting-edge technology. That also cannot be the Group Director's intention.

Allowance/Base Issue Fee Due and issue a patent on the present application on an expedited basis.

**C. The Group Director's Decision Harms Petitioners and Benefits the Junior Party**

Petitioners have an effective filing date of more than seven months before the effective filing date of the junior party competitor, GenPharm. Petitioners, however, have had only a single patent application indicated as containing allowable subject matter (the present application), and the majority of Petitioners' other applications related to the technology (including the present application), have been suspended pending potential interference(s). In contrast, the junior party competitor, GenPharm, has had two applications issued for closely related technologies. *See* U.S. Patent Nos. 5,545,806, issued August 13, 1996 (the "'806 Patent'"), and 5,569,825, issued October 29, 1996 (the "'825 Patent'").

It is submitted that the PTO has improvidently issued patents to the junior party competitor, GenPharm, in apparent disregard of M.P.E.P. § 2303, which provides that "[i]f an interference is declared, all applications having the interfering subject matter should be included." (*Emphasis supplied*). Further, M.P.E.P. § 2303 states:

The statutory requirement of first inventorship is of transcendent importance and every effort should be made to avoid the improvident issuance of a patent where there is an adverse claimant.

If the Group Director's Decision is allowed to stand, and if Section 2303 continues to be applied unfairly and incorrectly, this guiding policy of patent law will ultimately be frustrated.

The PTO has been on notice of the potential conflict between the applications of Petitioners and GenPharm since at least June 1994. In a Communication and Supplemental Information Disclosure Statement, filed on May 25, 1994, Petitioners' patent attorney alerted the PTO to a published GenPharm application and noted that there was overlapping subject matter claimed in the GenPharm applications and Petitioners' application. The M.P.E.P. clearly states:

Where subject matter found to be allowable in one application is disclosed and claimed in another application . . . the question of interference should be considered. The requirement of 37 [C.F.R. §] 1.601(I) that the conflicting applications shall contain claims for the same patentable invention should be interpreted as meaning generally that the conflicting subject matter is sufficiently supported in each application and is patentable to each applicant over the prior art.

M.P.E.P. § 2303.

Whether subject matter is "claimed" for the purposes of an interference is also discussed in the M.P.E.P.:

[T]he mere disclosure by an applicant of an invention which he or she is not claiming does not afford a ground for suggesting to that applicant a claim for the said invention based upon claims from another application that is claiming the invention. The intention of the parties to claim the same patentable invention, as expressed in the summary of the invention or elsewhere in the disclosure or in the claims, is an essential in every instance.

*Id.* Although Petitioners' pending claims contained certain differences from some of those claimed in the '806 Patent and the '825 Patent, Petitioners were at least pursuing generic claims directed to the same or substantially the same subject matter. On this point, the M.P.E.P. instructs:

The prosecution of generic claims is taken as an indication of an intention to cover all species disclosed which come under the generic claim.

M.P.E.P. § 2303. Accordingly, there is at least a question raised as to why the Examiner did not suggest claims to Petitioners before issuing the '806 Patent and the '825 Patent.

The PTO appears to be applying M.P.E.P. § 2303 selectively and in a manner that harms Petitioners and benefits the junior party competitor, GenPharm. On the one hand, the Group Director has applied Section 2303 in such a manner as to deny the Petitioners issuance of a patent based on the technology. On the other hand, the junior party competitor has obtained patents that relate to the technology in potential violation of the very same rule.

This apparently inconsistent application of the rule has allowed the junior party competitor to file a federal lawsuit against Cell Genesys' wholly owned subsidiary, Abgenix, asserting infringement of the '806 Patent and the '825 Patent. *See GenPharm International, Inc. v. Abgenix, Inc.*, Civil Action No. C 96-3861 MMC, filed on October 24, 1996 and as amended and supplemented on October 30, 1996.

Petitioners as senior parties are being treated unjustly in the application of PTO rules. In contrast, the junior party competitor, whose first effective filing date is more than seven months after Petitioners', is being, and has been, given the benefit of such PTO rules. In the interest of equity and

fairness, Petitioners respectfully request that the Group Director's Decision be reversed and that the Examiner and the Group Director be ordered to promptly issue a Notice of Allowance/Base Issue Fee Due and issue a patent based on the present application on an expedited basis.

### **III. REQUESTED RELIEF**

Petitioners respectfully request the following relief:

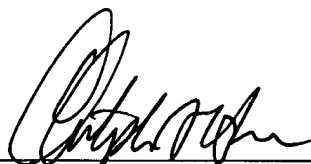
1. A Decision reversing the Decision of the Group Director;
2. Immediate removal of Petitioners' application from the Board of Patent Appeals and Interferences and withdrawal of the suspension order of March 1, 1996. (It is noted that more than six (6) months have elapsed since the suspension order was issued);
3. An order to the Examiner and the Group Director directing expedited mailing of a Notice of Allowance and Base Issue Fee Due form to the Petitioners;
4. Upon Petitioners' payment of the Base Issue Fee and submission of Formal Drawings, an order placing the application on Special Status to ensure issuance of the patent on an expedited basis;
5. Revocation of the Suspension Orders in Petitioners' related patent applications, including Serial Nos. 07/922,649, 08/112,848, 08/464,582, 08/463,191, and 08/462,513 and an order granting expedited examination and issuance of such applications where appropriate; and
6. Any such other relief as deemed just, proper, and consistent with Petitioners' requested relief.

Should the Assistant Commissioner affirm the Group Director's Decision, Petitioners respectfully request that the Assistant Commissioner place on the record that the Decision constitutes a final administrative action and indicate that Petitioners have exhausted their administrative remedies before the PTO.

Should the Assistant Commissioner have any questions, or if a personal interview discussing the issues raised herein would be productive, the Assistant Commissioner is urged to contact the undersigned at the number appearing below.

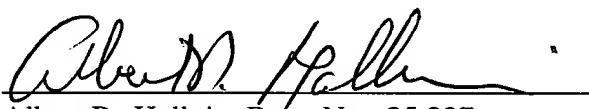
Dated: 11/13/96

**ABGENIX, INC.**  
322 Lakeside Drive  
Foster City, CA 94404  
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\_\_\_\_\_  
Christopher A. Hare, Reg. No. 37,637  
**PATENT COUNSEL, ABGENIX, INC.**

Dated: 11/13/96

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